



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Telephone (973) 526-6001

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
September 7, 2000

WARNING LETTER

Mr. Harold Robinson
President
Cassidy's Seafood Inc.
18th and Bayview
Barnegat Light, NJ 08006

FILE NO: 00-NWJ- 53

Dear Mr. Robinson:

On May 18-20, 2000, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility located at the above address. The inspection was conducted to determine compliance with FDA's seafood processing regulations (Title 21 of the Code of Federal Regulations (CFR) Part 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented deficiencies which cause your scombrototoxin-forming seafood processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. You must have a HACCP plan that lists all of the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrototoxin-forming species of fish (yellowfin and bigeye tuna, wahoo, mahi-mahi) lists the critical limit at Receiving and Delivery, "Fish above [redacted] degrees Fahrenheit". This critical limit should read "Fish below [redacted] degrees Fahrenheit" and this critical limit alone is not adequate to control scombrototoxin (histamine) formation. Adequate receiving critical limits should also include parameters for harvest vessel records or histamine testing and sensory evaluation.
2. You must have a HACCP plan that lists all of the necessary critical control points, to comply with 21 CFR 123.6(c)(2). However your firm's HACCP plan for tuna, mahi-mahi, and wahoo does not list cooler storage as a critical control point to control the food safety hazard of histamine.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.


You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include seizure or injunction under the Act. In addition, failure to correct the above

deficiencies may affect your firm's ability to obtain European Union (EU) certificates. As you know, FDA, as a service to the U.S. seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU food safety requirements. Unless the above deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipments.

Please notify this office within 15 working days of receipt of this letter. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to the Food and Drug Administration, Attention: Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054, telephone (973) 526-6006.

Sincerely,


Douglas I. Ellsworth
District Director
New Jersey District

slm:DBR